

***United States Court of Appeals  
for the Second Circuit***



**APPELLANT'S  
BRIEF &  
APPENDIX**



*Original*

*Affidavit of Truth*

**74-1999**

To be argued by  
CYRIL HYMAN

**United States Court of Appeals  
FOR THE SECOND CIRCUIT  
Docket No. 74-1999**

UNITED STATES OF AMERICA,

*Plaintiff-Appellee,*

—against—

DIAPULSE CORPORATION OF AMERICA, also known as the  
DIAPULSE MANUFACTURING CORPORATION OF AMERICA,  
a corporation,<sup>§</sup>

*Defendant-Appellant.*

ON APPEAL FROM THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF NEW YORK

**BRIEF AND APPENDIX FOR PLAINTIFF-APPELLEE**

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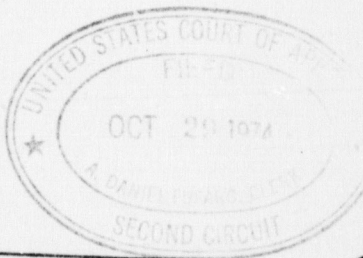
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**United States Court of Appeals  
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**Docket No. 74-1999**

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UNITED STATES OF AMERICA,  
*Plaintiff-Appellee,*  
—against—

DIAPULSE CORPORATION OF AMERICA, also known as the  
DIAPULSE MANUFACTURING CORPORATION OF AMERICA,  
a corporation,  
*Defendant-Appellant.*

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**BRIEF FOR PLAINTIFF-APPELLEE**

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**Counterstatement of the Issues Presented**

1. Whether the district court abused its discretion in revising a permanent injunction previously in effect and in entering a more comprehensive and specific permanent injunction under the Federal Food, Drug, and Cosmetic Act.
2. Whether the permanent injunction appealed from is consistent with the purposes of the permanent injunction previously in effect and the Federal Food, Drug, and Cosmetic Act.

## Counterstatement of the Case

Because the defendant contends that the district court (Dooling, J.) acted without proper authority in entering a more comprehensive injunction against it than the one previously in effect, we believe a full discussion of the facts is required so that this Court can adequately consider the matter.

### A. Background

*Seizure Action.* On December 17, 1965, pursuant to the seizure provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 334 (the "Act"), a Libel of Information was filed by the United States in the United States District Court for the Northern District of Georgia, against an article of device known as Diapulse ("the Diapulse"). The Diapulse<sup>1</sup> was alleged to be misbranded within the meaning of 21 U.S.C. 352(a) in that printed matter which constituted its labeling contained statements falsely representing and suggesting that the device was adequate and effective for some 121 purposes and conditions. Diapulse Corporation of America, the defendant in the instant case, intervened as claimant and answered the Libel. On its motion, the case was removed to the United States District Court for the District of Connecticut where it was tried to a jury,

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<sup>1</sup> As described by Judge Dooling in his memorandum and order dated May 7, 1974, the Diapulse device " \* \* \* is a short wave, high frequency, electromagnetic device operating at 27.12 megahertz, and is operable from a standard 117 volt 60 cycle AC 5½ ampere electric current, the kind delivered by American utilities to residential and commercial properties" (68A). Page references in parentheses with the notation A refer to pages of the appellant's appendix. As described by Judge Rosling in his opinion of June 12, 1972, the Diapulse was claimed to be adequate and effective for treatment of " \* \* \* a lengthy list of diseases and claims of stimulating, enhancing, restoring, reenergizing, increasing, revitalizing, various systems, functions, mechanisms, etc. of the human body \* \* \*" (27A).

which returned a general verdict for the government. In addition, in answer to special interrogatories pursuant to Rule 49(b) of the Federal Rules of Civil Procedure, the jury affirmatively marked as false and misleading 49 of the 121 claims charged; no markings were made respecting the remaining 72 claims. Judge Rosling found that, contrary to the spirit and letter of the Connecticut injunction, Diapulse Corporation's continued use of 25 of the remaining claims left unanswered by the jury under explicit authority of the Court was "... circular with arrogant effrontery, wholly contrary to the spirit and letter of Judge Blumenfeld's injunction..." (40A). Judge Dooling stated that the Connecticut jury " \* \* \* made no finding that the device had any therapeutic utility as to any of the ailments or conditions left blank" (84A).

Judgment for the government in the Connecticut seizure action was entered on March 31, 1967, condemning the Diapulse as misbranded and ordering its destruction. An amended judgment allowing the defendant the opportunity to bring the device into compliance with the provisions of the Act, under the supervision of the United States Food and Drug Administration ("FDA") was entered in the Connecticut action on April 26, 1967. The Diapulse device condemned in the seizure action was never brought into compliance with the law and the FDA has never given its consent to further distribution of the device in interstate commerce (44A). On January 30, 1968, this Court affirmed the judgment and the District Court's denial of appellant's motion for judgment notwithstanding the verdict or a new trial. *United States v. An Article of device . . . Diapulse*, 389 F.2d 612 (2d Cir.), cert. denied, 392 U.S. 907 (1968).

*Injunction Action.* Since the Diapulse continued to be promoted for, among others, the same claims specifically adjudicated false and misleading in the seizure action, the government instituted this action pursuant to the injunction provisions of the Act, 21 U.S.C. 332, in April, 1968,

in the Eastern District of New York (1A). Trial commenced in June, 1971, before the late District Judge George Rosling, and after 11 days of trial was adjourned over the summer to October 12, 1971, at which time some 30 additional days of trial testimony was had. At the close of its case on October 26, 1971, the government moved for a preliminary injunction.

Subsequently, the trial continued and on December 8, 1971, after hearing and reading some 10,000 and more pages of testimony (46A) and after hearing the bulk of the evidence, Judge George Rosling filed findings of fact and conclusions of law and an order granting the preliminary injunction (3A). Appellant appealed from the preliminary injunction which was affirmed by this Court on March 20, 1972. *United States v. Diapulse Corporation of America*, 457 F.2d 25 (2d Cir. 1972). In affirming, this Court stated:

"The device had been found to be generally misbranded, in violation of the statute, and in addition, a jury of laymen had found 49 specific claims to be false or misleading. Yet the company continued its brazen advertising scheme, failing to inform its buyers and lessors of the litigation or of the dispute in medical circles about the machine's efficacy. It did not prove the machine's effectiveness or relabel it to the FDA's satisfaction. The company's persistence in marketing the device makes it highly likely that the prohibited activity will cease only on the issuance of a blanket prohibition on shipment" (48A). *United States v. Diapulse Corporation of America*, *supra*, 457 F.2d at 29.

On July 18, 1972, the district court entered a permanent injunction prohibiting the defendant from, among other things, shipping the misbranded Diapulse in interstate commerce (61A). On September 15, 1972, the defendant

appealed from the permanent injunction which this Court affirmed without opinion. *United States v. Diapulse Corporation of America*, 485 F.2d 677 (2d Cir. 1973), *cert. denied*, *Diapulse Corporation of America v. United States*, — U.S. —, 94 S.Ct. 1938 (1974).

## B. This Appeal

This appeal grows out of an action for criminal contempt alleging violations of both preliminary and permanent injunctions in effect, respectively, from March 20, 1972 and July 18, 1972. The contempt action primarily involved allegations that the appellant violated the permanent injunction of July 18, 1972, by the interstate shipment of what the defendant had styled "P/EmF" modification kits. The kits were intended to be used to modify existing Diapulse devices. The modified device would incorporate an extended range of power output while retaining the capability to be operated and to function as a Diapulse (65A-66A, 76A-79A).

On April 12, 1974, the contempt action was dismissed by Judge John F. Dooling, Jr., on the grounds that the Government had failed to show a criminal intent to circumvent the permanent injunction (93A-94A). Subsequent to that ruling, however, Judge Dooling continued hearing evidence on cross-motions by the parties for modification of Judge Rosling's permanent injunction of July 18, 1972, pursuant to its paragraph VI (64A).<sup>2</sup>

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<sup>2</sup> "VI. The Court retains jurisdiction of this case for the purpose of enforcing or modifying this Permanent Injunction, and for the purpose of granting such additional relief at the instance of any of the parties as may hereafter appear necessary or appropriate."

On May 7, 1974, the district court entered its Memorandum Incorporating Findings of Fact and Order (65A). Among other things, the district court found that (79A):

" \* \* \* the preponderance of evidence is that use of the modification kits as sent out in June, July and the first part of August 1972, in accordance with the accompanying instructions, gave the modified Diapulse devices a design output, as P/EmF devices, when operating at 80 to 600 pulse frequency, identical with that of the Diapulse D-101 and D-102" (79A).

It further found that (94A):

"[w]hile the shipments of the kits were not of themselves shown to constitute criminal contempts that could be given to the jury on all of the evidence it must be concluded that shipments of the P/EmF kits, and the use of equipment converted through use of the kits, constituted evasion and not avoidance of the strictures of the permanent injunction and its purpose."

Accordingly, the district court concluded that "... the defendants are entitled to a clear command and the government to a rigorous order so that there cannot be any evasion and extirpation is effective" (97A). Following the suggestion of the district court (99A), both parties proposed language for a revised permanent injunction. Judge Dooling heard argument on the settlement of the order on July 3, 1974 (2A).

The permanent injunction currently in effect was entered July 18, 1974, and prohibits, among other things, the interstate shipment of the Diapulse and modified Diapulse devices known as the P/EmF which Judge Dooling had found to be both in law and in fact the same as the Diapulse (79A).

On July 19, 1974, Judge Dooling denied in all respects the defendant's motion for a stay of the present injunction (140A). On July 24, 1974, the appellant appealed from the present injunction (141A).

## ARGUMENT

### POINT I

The permanent injunction should be affirmed. The district court properly acted within its discretion in revising a permanent injunction previously in effect and in entering a more comprehensive and specific permanent injunction under The Federal Food, Drug, and Cosmetic Act.

This appeal must be considered in the light of the high purpose and intent of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.* In previously affirming the preliminary injunction against appellant, this Court reiterated the well-established view that the Act relates to the public health and must be applied broadly in order to effect its remedial purpose. *United States v. Diapulse Corporation of America*, 457 F.2d 25, 27-8 (2d Cir. 1972), where this Court pointed out that:

[t]he Food, Drug, and Cosmetic Act has as its purpose the protection of the public from products not proven to be safe and effective for their alleged uses and the safeguarding of the public health by enforcement of certain standards of purity and effectiveness. The reach of the Act is broad and the provisions, touching the public interest in a direct way, are to be given a liberal construction.

In considering the propriety of an injunction which restrains individuals from violating the law of the United States, this Court has long followed the rule that where an injunction is authorized by statute it is enough that the statutory conditions are satisfied. *United States v. Diapulse Corporation of America*, *supra*, 457 F.2d at 27, 28;

*Henderson v. Burd*, 133 F.2d 515, 517 (2d Cir. 1943); *United States v. Adler's Creamery, Inc.*, 110 F.2d 482 (2d Cir. 1940); *Securities and Exchange Commission v. Torr*, 87 F.2d 446, 450 (2d Cir. 1937).

Thus, in determining whether a statutory injunction shall issue, this Court recognized that it is not bound by the same rules as pertain to private litigation. *United States v. Diapulse Corporation of America*, *supra*, 457 F.2d at 27, 28. While the grant or denial of such an injunction is not mandatory but discretionary, the discretion involved is to be exercised in light of the objectives of the statute. *Hecht Co. v. Bowles*, 321 U.S. 321, 330 (1944); *United States v. W. T. Grant Co.*, 345 U.S. 629 (1953).

Similarly, motions to modify injunctive relief are addressed to the discretion of the court, and the disposition made by the trial court will not be disturbed on appeal in the absence of an abuse of discretion. *System Federation v. Wright*, 364 U.S. 642, 647 (1961); *Securities and Exchange Com'n v. Thermodynamics, Inc.*, 464 F.2d 457, 459 (10th Cir. 1972), *cert. denied*, Volume 410 U.S. — Part 2, 927 (1973). This rule obtains here, for appellant has made no showing that the district court abused its discretion in granting the present permanent injunction.

**A. The district court had authority to modify the permanent injunction which, by its own terms, anticipated future modifications.**

Appellant contends that the district court in this case had no power to change the decree of permanent injunction previously in effect except in defendant's favor by vacating all or part of the injunction (Appellant's Brief, Point I). In support of its argument, defendant contends that an injunction, not altered or amended within the ten

and twenty day periods<sup>3</sup> provided in Rules 50, 52 and 59 of the Federal Rules of Civil Procedure, can be modified only under Rule 60(b), which operates "for a reasonable time" and which only authorizes a court to "relieve" a party from a judgment. Quoting dictionary definitions (Appellant's Brief, pp. 22-23), appellant argues that the district court thus had the power only to mitigate or ease the restraints imposed by the previous permanent injunction.

On the contrary, the authority of the issuing court over a continuing decree of injunction derives from the inherent equitable power of the federal courts. The power of the court to modify a continuing decree of injunction is well-established. *United States v. United Shoe Machinery Corp.*, 391 U.S. 244, 248 (1968); *System Federation v. Wright*, *supra*, 364 U.S. 642; *United States v. Swift & Co.*, 286 U.S. 106 (1932). As the Supreme Court declared in *United States v. Swift & Co.*, *supra*, 286 U.S. at 114.

[w]e are not doubtful of the power of a court of equity to modify an injunction in adaptation to changed conditions . . . Power to modify the decree was reserved by its very terms, and so from the beginning went hand in hand with its restraints. If the reservation had been omitted, power there still would be by force of principles inherent in the jurisdiction of the chancery. A continuing decree of injunction directed to events to come is subject always to adaptation as events may shape the need [citation of cases omitted].

Moreover, the decision of the Court of Appeals in *Ridley v. Phillips Petroleum Co.*, 427 F.2d 19, 23 (10th Cir. 1970), rejecting the time limitation of Rule 60(b) as inapplicable

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<sup>3</sup> The government moved for the modification of the previous injunction after the dismissal of the contempt action, long after these periods had expired.

to the modification of an injunction, further demonstrates that the Rule imposes no limitation on the inherent equitable power of the federal courts to modify a continuing decree of injunction. See also, *Scott v. Young*, 307 F. Supp. 1005, 1007 (E.D. Va., 1969), *aff'd*, 421 F.2d 143 (4th Cir.), *cert. denied*, 398 U.S. 929 (1970).

Similarly without merit is appellant's subsidiary argument (Appellant's Brief, pp. 30-33) that no precedent recognizes the power of a federal court to impose additional restraints through the modification of a continuing decree of injunction. In support of this argument appellant cites *United States v. Swift & Co.*, *supra*; and *System Federation v. Wright*, *supra*.<sup>4</sup> But these are cases in which the enjoined party sought relief and this argument falls within appellant's failure to distinguish the injunction modification involved in *Scott v. Young*, *supra*. While appellant refers to this decision as an "exception", it is squarely contrary to appellant's contention that the district court can change an injunction only in the interest of the enjoined party.

In any event, appellant obviously ignores the Supreme Court's decision in *United States v. United Shoe Machinery Corp.*, *supra*, 391 U.S. 244. There the government petitioned for additional injunctive relief on the grounds that the injunction then in effect had not achieved the relief sought. The district court denied the government's petition, holding that under *United States v. Swift & Co.*,

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<sup>4</sup> Defendant also cites *Stewart Die Casting Corp. v. National Labor Relations Board*, 129 F.2d 481 (7th Cir. 1942). That decision is inapposite. It involves an attempt by a labor union to obtain modification of an order of the National Labor Relations Board by petitioning to intervene in the employer's action to have the order set aside. The petition to intervene was denied.

*supra*, its power to modify the existing injunction was limited to cases involving a clear showing of grievous wrong evoked by new and unforeseen conditions, a proposition also advanced by the appellant here (Appellant's Brief, pp. 33-36). The Supreme Court rejected this interpretation, holding *Swift* in no way restrictive of the district court's power to grant the additional relief requested by the government. Moreover, the Supreme Court in that case held the trial court responsible to determine whether "adequate relief" had been achieved and, if not, to modify the decree to achieve such relief "with all appropriate expedition." *United States v. United Shoe Machinery Corp.*, *supra*, 391 U.S. at 252. Accordingly, the defendant clearly misplaces its reliance on *United States v. Swift & Co.*, *supra*, inasmuch as the Supreme Court in *United States v. United Shoe Machinery Co.*, *supra*, 391 U.S. at 248 declared that:

Swift teaches that a decree may be changed upon an appropriate showing, and it holds that it may *not* be changed in the interest of the defendants if the purposes of the litigation as incorporated in the decree . . . have not been fully achieved. [Emphasis in original.]

In addition, the decision of this Court in *King-Seeley Thermos Co. v. Alladin Industries, Inc.*, 418 F.2d 31, 35 (2d Cir. 1969), pointed out that:

[W]hile changes in fact or in law afford the clearest bases for altering an injunction, the power of equity has repeatedly been recognized extending also to cases where a better appreciation of the facts in the light of experience indicates that the decree is not properly adapted to accomplishing its purposes.

Finally, appellant argues that the affirmance on appeal of the previous injunction deprived the district court of jurisdiction to change the decree (Appellant's Brief, p. 41).

However, this argument clearly fails to acknowledge the well-established authority and responsibility of the issuing court over an injunction. Thus, the Supreme Court in *System Federation v. Wright*, *supra*, 364 U.S. at 647, explained that:

[t]here is . . . no dispute but that a sound judicial discretion may call for the modification of the terms of an injunctive decree if the circumstances, whether of law or fact, obtaining at the time of its issuance have changed, or new ones have since arisen. The source of the power to modify is of course the fact that an injunction often requires continuing supervision by the *issuing court and always a continuing willingness to apply its powers and processes on behalf of the party* who obtained that equitable relief . . . [Emphasis supplied.]

Accord: *United States v. United Shoe Machinery Corp.*, *supra*, 391 U.S. at 250; *Securities and Exchange Com'n v. Thermodynamics, Inc.*, *supra*, 464 F.2d at 460; *Ridley v. Phillips Petroleum Co.*, *supra*, 427 F.2d at 23; *King-Secley Thermos Co. v. Aladdin Industries, Inc.*, *supra*, 418 F.2d at 34.<sup>5</sup>

**B. The district court's findings of fact justify modification of the permanent injunction previously in effect.**

Appellant argues (Appellant's Brief, pp. 33-41) that even if the district court had power to modify the perman-

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<sup>5</sup> The jurisdiction of the District Courts to modify its injunctions, is well settled by the above cited cases. Not quite as clear, however, is the District Court's jurisdiction over a judgment which by its terms did not anticipate future modifications and contained no reservation of jurisdiction in the District Court, and where, in addition, a subsequent Court of Appeals mandate is involved. See *Doe v. Hodgson*, — F.2d —, Slip Opin. Application, p. 4901, 4903 (2nd Cir., July 22nd, 1974).

ent injunction previously in effect, it could do so only upon the finding of an extreme change in circumstances, citing in support *United States v. Swift & Co.*, *supra*, *System Federation v. Wright*, *supra*, and *Schildhaus v. Moe*, 335 F.2d 529 (2d Cir. 1964).<sup>6</sup> Each of these cases, however, involves efforts to modify injunctive restraints in favor of the enjoined parties and must be read in that context. *United States v. United Shoe Machinery Corp.*, *supra*, 391 U.S. at 248.

Contrary to appellant's argument, a continuing decree of injunction may be changed upon an *appropriate showing* and if the district court determines that a decree has not achieved the relief to which the government is entitled, it is the duty of the court to "... modify the decree so as to achieve the required result with all appropriate expedition." *United States v. United Shoe Machinery Corp.*, *supra*, 391 U.S. at 252. Here, the district court has made precisely such a determination.

As pointed out by Judge Dooling, there is no genuine controversy as to the facts involved (66A). On July 18, 1972, the previous injunction was entered prohibiting the interstate shipment of misbranded Diapulse or any similar articles of device (61A). Prior to the entry of the previous injunction, the defendant "evolved the concept of the P/EmF" (76A) and while that injunction was in full force and effect, the defendant shipped P/EmF modification kits to purchasers within the United States (67A). The kits consisted of parts intended to provide a relatively inexpensive means of converting the Diapulse to a device called a P/EmF which would incorporate an additional output range while at the same time allowing the modified

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<sup>6</sup> Defendant also cites *Stewart Die Casting Corp. v. National Labor Relations Board*, 129 F.2d 481 (7th Cir. 1942), but that case is inapposite as explained in the note at page 10, *supra*.

device to be operated exactly as a Diapulse device (76A-79A). Judge Dooling, however, found that (80A):

[a]ny possessor of a P/EmF device produced through the use of the modification kit to modify a Diapulse . . . who had theretofore used a Diapulse device for experimentation, test, or as a therapeutic instrument, could use the P/EmF device exactly as he had used the Diapulse device without any change whatever in procedures.

Furthermore, Judge Dooling concluded (94A):

. . . shipments of the P/EmF kits, and the use of equipment converted through use of the kits, constituted evasion and not avoidance of the strictures of the permanent injunction and its purpose.

Accordingly, the district court declared that "the defendants are entitled to a clear command and the government to a rigorous order so that there cannot be any evasion and extirpation is effective" (97A).

Based on the findings of fact and conclusions of law made by Judge Rosling on December 8, 1971 and June 9, 1972, and the finding he made on May 7, 1974, Judge Dooling entered the present injunction on July 18, 1974 (125A). The district court's Memorandum Incorporating Findings of Fact and Order, entered May 7, 1974 (65A), establishes that in revising the previous injunction the court intended more effectively to implement the purposes of the previous injunction which was affirmed by this Court on appeal *United States v. Diapulse Corporation of America, supra*, 485 F.2d 677 and which had been in effect for the preceding two years. While the appellant characterizes the present injunction as "far more drastic and extensive" (Appellant's Brief, p. 2) than the previous injunction, a comparison of the two shows that Judge Dooling entered an order more comprehensive and specific in its scope and

terms, but one which is entirely consistent with the previous injunction.

Section II of the previous injunction defined the device to which the injunction applied as "an electromagnetic generator similar to conventional medical diathermy but differing from it in that its output is pulsed and in that it lacks the energy output of conventional medical diathermy" (61A). Under this definition appellant shipped P/EmF modification kits to convert the Diapulse to a device which incorporated an additional and slightly greater output range than the Diapulse but which was capable of being operated exactly as a Diapulse (80A). Consequently, the district court revised section II to define, among other terms, a "prohibited device" to include the Diapulse, the P/EmF, and other similar devices unless they meet specified requirements.

Appellant argues (Appellant's Brief, pp. 6-7, 12-13, 42) that section II thus prohibits it from marketing in interstate commerce conventional medical diathermy devices without FDA pre-clearance of labeling.<sup>7</sup> On the contrary, the present injunction under Section II(E) carefully defines the prohibited devices to which the injunction applies (126A-127A) and, according to the district court's findings of fact (93A), the prohibited device to which the present injunction applies excludes those capable of meeting the generally accepted standards of conventional diathermy. Thus, the requirements for exclusion are precisely defined by section II(E)(3) (127A). Accordingly, appellant's argument that it is prohibited from marketing devices that have all the capabilities of conventional diathermy is contradicted by the present permanent injunction and the district court's findings of fact.

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<sup>7</sup> This argument is curious in view of the district court's finding that the appellant is not interested in diathermy, diathermy therapy, or diathermy modalities (70A).

Section III of the present injunction is virtually identical to the same section of the previous injunction. This section prohibits the shipment in interstate commerce of prohibited devices which are misbranded within the meaning of the Act, and also prohibits the misbranding of devices which are held for sale after shipment in interstate commerce.

Section IV, paragraph (A), of the present injunction prohibits the shipment of prohibited devices except upon approval by FDA of labeling for such devices prior to shipment. The same provision appeared in Section IV of the previous injunction and the same requirements appeared in the preliminary injunction affirmed by this court. See *United States v. Diapulse Corporation of America, supra*, 457 F.2d at 29-30. Paragraph (B) of Section IV defines the term "adequate scientific evidence" for purposes of the application of paragraph (A).

Paragraph (C) of Section IV provides terms and conditions for the exemption of shipments of prohibited devices for investigational or research purposes. Such terms and conditions are justified by the district court's findings that appellant has continued to encourage and support research devoted to exploring any therapeutic usefulness of the Diapulse (71A).

Paragraph (D) of Section IV requires that the appellant bring prohibited devices as defined by present Section II(E)(3) into compliance with the law pursuant to the approval of labeling provision of Section IV(A). Section II(E)(2) primarily defines prohibited devices to include P/EmF devices and P/EmF modification kits. Thus, the requirement of Section IV(D) merely extends the approval of labeling provision to devices which the district court found had been shipped in "evasion and not avoidance of the strictures of the permanent injunction

and its purpose" (94A). While appellant apparently assumes these number some 4,000 devices and argues that this requirement will impose a tremendous burden (Appellant's Brief, pp. 13, 45), the appellant's president testified (1B) <sup>\*</sup> and the district court found (67A) that the defendant shipped 297 of the P/EmF modification kits to purchasers within the United States. This indicates that only some 300 devices are likely to be subject to this provision. Moreover, the requirement of paragraph (D) that the appellant cause such devices to be returned to its headquarters or other suitable facilities for the compliance operation is clearly reasonable for the purposes of FDA supervision of such compliance activities as required by Section IV(D)(3) of the present injunction.

Section V of the present injunction requires appellant to notify the Food and Drug Administration of each of the facilities it utilizes for manufacturing or storing medical devices and authorizes FDA access to such facilities and records for purposes of inspection.

These provisions are included for the effective monitoring by FDA of the appellant's compliance with the terms of the injunction. Moreover, the appellant's objection to the inspection provision fails to account for the testimony of the appellant's president which acknowledged the refusal of two FDA inspections following the entry of the previous permanent injunction in July 1972 (1B). The district court's findings clearly show that at the same time as the FDA inspections were being refused, appellant was engaged in the distribution of modification kits for Diapulse devices which had been previously shipped in interstate commerce (65-66A).

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<sup>\*</sup> References succeeded by the letter "B" refer to Appellee's Appendix.

Section VI of the present injunction requires appellant to provide notice to specified persons of the provisions of the present injunction and to advise the United States Attorney of the identity of the persons so notified. Virtually the same provision was included in the previous injunction as Section V (63A), and appellant argues (Appellant's Brief, p. 47) that further notification is not required, since notice was provided in accordance with the terms of the previous injunction. On the contrary, the district court ruled specifically that a notification provision functioning as the notification provision of the previous injunction should be included in the present injunction (99A). Moreover the court found that persons with prohibited devices in their possession continue to retain Diapulse literature (76A). Accordingly, notification of the provisions of the *present* injunction should be required.

Under Section VII of the present injunction the court retains jurisdiction for the purpose of enforcing or modifying the injunction. Section VIII of the present injunction grants costs to the government. The same provisions were included as Sections VI and VIII of the permanent injunction previously in effect (64A).

## POINT II

**The present permanent injunction is consistent with the purposes of the Federal Food, Drug, and Cosmetic Act.**

Appellant argues (Appellant's Brief, pp. 42-47) that a number of the provisions of the present permanent injunction are inconsistent with the Act. An examination of these provisions, however, shows that each is in accord not only with the purposes of the Act but also with the purposes of the previous permanent injunction.

**A. FDA approval of labeling for prohibited devices.**

The present injunction prohibits appellant from, among other things, shipping prohibited devices in interstate commerce unless and until it assembles the scientific evidence on which labeling of such devices is to be based, prepares the labeling in full conformity with the Act, and submits the evidence and labeling to FDA and obtains approval thereof in writing (130A). Appellant asserts (Appellant's Brief, pp. 6-7, 12-13, 42) that FDA approval of labeling for prohibited devices applies to no other manufacturer and is not provided for by statute or regulation.

The preliminary injunction against appellant listed as a condition for the lifting of the injunction FDA approval of labeling for the Diapulse condemned in the prior seizure action. In appealing the preliminary injunction, appellant argued that this condition imposed a requirement not authorized by the Act. *United States v. Diapulse Corporation of America*, *supra*, 457 F.2d at 29. Since the effect of these provisions in the preliminary and the present injunction is the same, the defendant is here rearguing a legal issue decided adversely to it on the appeal of the preliminary injunction and attempting to overturn what is now the law of this case. *Kable v. United States*, 175 F.2d 16, 18 (2d Cir. 1949); *Prudential Insurance Company of America v. Morrow*, 368 F.2d 813 (5th Cir. 1966).

**B. Specification of prohibited devices deemed to be held for sale.**

Section III(B) of the present injunction prohibits acts with respect to prohibited devices while such devices are held for sale after shipment in interstate commerce which result in the devices being misbranded, and provides that prohibited devices in the possession of practitioners licensed by law to use or order the use of the devices shall be deemed to be held for sale (129A). Appellant asserts

(Appellant's Brief, pp. 7, 43-44) that this is a new provision which has no application to it and argues that practitioners using such devices for the treatment of patients are not holding such devices for sale within the meaning of the Act. On the contrary, Section III(B) of the previous injunction applied to devices held for sale as does Section III(B) of the present injunction, which has been revised merely to specify the most significant class of devices which are deemed held for sale for purposes of the injunction.

While appellant argues (Appellant's Brief, p. 44) that a sale is a transfer of title, it has long been held that the phrase "held for sale" carries no technical or restrictive meaning and all articles subject to the Act and held for purposes other than personal consumption are "held for sale". *Hipolite Egg Co. v. United States*, 220 U.S. 45, (1911); *United States v. Kocmond*, 200 F.2d 370, 372-3 (7th Cir. 1952), cert. denied, 345 U.S. 924 (1953). Thus, in *United States v. An Article of Device . . . Cameron Spitler*, 261 F. Supp. 243, 246 (D. Neb. 1966), the court noted that the device involved was misbranded while "held for sale" within the meaning of the Act, for although the device was never sold in the commercial sense, the device was used by a practitioner in the treatment of patients. Similarly, in *United States v. Ten Cartons . . . Horsey Tablets*, 152 F. Supp. 360 (W.D. Pa., 1957), a misbranded drug was said to be held for sale and was condemned despite the fact that it was not itself sold to patients, but was used as part of the treatment at a cancer clinic.

Appellant also attempts to rely in support of its argument on *United States v. Sullivan*, 332 U.S. 689 (1948), despite its holding that an article is subject to the Act from the time of its introduction into interstate commerce until it is delivered to the ultimate consumer. That decision thus supports the proposition that a device used

by a licensed practitioner in the treatment of patients is held for sale. Accordingly, it is clearly reasonable to provide for purposes of the present injunction that prohibited devices in the possession of practitioners licensed by law to use or order the use of such devices shall be deemed to be held for sale. Such a specification obviously provides both the government and appellant a more specific standard by which to measure appellant's conduct under the injunction.

**C. Return of certain prohibited devices for compliance purposes.**

Section IV(D) requires the defendant to bring the prohibited devices as defined by Section II(E)(2) previously shipped in interstate commerce into compliance with the law pursuant to the approval of labeling provision of Section IV(A). Section II(E)(2) defines prohibited devices to include the modified Diapulse device known as the P/EmF and the P/EmF modification kit (126A-127A) and Section IV(D)(1) requires that these be returned by the appellant to its headquarters or other suitable facilities for the compliance operation (133A). Since the devices specified are those which were shipped after the entry of the injunction previously in effect (66A-67A), the requirement of Section IV(D) merely extends the approval of labeling provision to devices which the district court found had been shipped in "evasion . . . of the strictures of the permanent injunction and its purpose" (94A).

While appellant argues (Appellant's Brief, p. 44) that there is no provision in the Act requiring such a return of devices, this Court rejected appellant's similar argument that the Act does not authorize "pre-clearance" of medical devices on the grounds that appellant was not attempting to market the device for the first time and that corrective measures are required before the device can be shipped in commerce. *United States v. Diapulse Corporation of*

*America, supra*, 457 F.2d at 29. So here, the devices involved were shipped in "evasion" of the previous injunction, a finding appellant makes no effort to controvert, and clearly, require "corrective measures" inasmuch as the lower court found that the facts do warrant the use of the P/EmF as a heat treatment device (86A).

Since the "corrective measures" required by Section IV(D) extend to misbranded devices, the provision is clearly consistent with the purposes of the Act. Indeed, similar injunctive relief requiring the return of violative articles shipped in interstate commerce has been ordered in other cases arising under the Act. *United States v. Dianovin Pharmaceuticals*, 342 F. Supp. 724 (D. P.R., 1972), *aff'd*, 475 F.2d 100 (1st Cir.), *cert. denied*, 414 U.S. 830 (1973); *United States v. Lit Drug Company*, 333 F. Supp. 990 (D. N.J., 1972); *United States v. Lanpar Co.*, 293 F. Supp. 147 (N.D. Tex., 1968). Moreover, such relief accords with the long recognized power of the court in equity to provide complete relief in the light of statutory purposes. *Mitchell v. Robert De Mario Jewelry, Inc.*, 361 U.S. 288, 292 (1960); *Porter v. Warner Holding Co.*, 328 U.S. 395, 403 (1946); *United States v. Diapulse Corporation of America, supra*, 457 F.2d at 27-29; *Hodgson v. International*, — F.2d —, Slip Opin. 1158, p. 5110 (2d Cir. Aug. 2nd, 1974).

#### **D. FDA Inspectional Authority**

Section V(B) of the present injunction requires the defendant to grant duly authorized FDA employees access to each of the facilities it utilizes for manufacturing or storing medical devices for the purpose of inspecting such facilities at reasonable times during regular working hours, within reasonable limits and in a reasonable manner, and further provides that such inspection may extend to records bearing on whether any prohibited devices have been or are being manufactured, assembled, processed, packed,

transported or held in such place. As indicated in part B of the preceding section, such a provision is clearly reasonable to enable FDA to effectively monitor the appellant's compliance with the terms of the present injunction.

Moreover, appellant's argument (Appellant's Brief, pp. 13-14, 45-47) that the inspection provision of the present injunction goes beyond the inspectional authority provided by the Act with regard to devices is irrelevant here. Through the injunction, the district court ordered inspectional authority similar to that provided by 21 U.S.C. 374 as to drug manufacturers, and the appellant identifies no basis on which it may be concluded that the authorization is an abuse of the district court's discretion.<sup>9</sup> Further, appellant's suggestion (Appellant's Brief, pp. 13-14) that the inspection provision violates the Fourth Amendment to the Constitution is similarly unsupported and ignores those cases in which similar inspectional authority has been ordered. *United States v. Dianovin Pharmaceuticals, supra*, 342 F. Supp. at 731; *United States v. Lit Drug Company, supra*, 332 F. Supp. at 997 to 998; *United States v. Nutrition Services, Inc.*, 227 F. Supp. 375, 392 (W.D. Pa., 1964).

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<sup>9</sup> The district court recognized that "the advance clearance requirement [section IV(A)] is not normally required for devices but is exceptionally required in this case and consciously borrows from new drug procedures (99A)." Appellant has identified no reason why the inspectional authority ordered by the court may not also properly borrow from the drug procedures of the Act, and indeed it cannot, since this court has declared that an "... injunction may sweep broadly in its prohibition if that is necessary to enjoin future violations which appear likely to occur." *United States v. Diapulse Corporation of America*, 457 F.2d 25, 29 (2d Cir. 1972).

## CONCLUSION

On the basis of the foregoing, it is respectfully urged that the permanent injunction appealed from be affirmed.

Dated: October 25, 1974

Respectfully submitted,

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## APPENDIX

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1-b

**Testimony of Jesse Ross (cross-examination)**

April 17, 1974

1043 \* \* \* \* \*

Q. Do you recall the July of 1972, after the injunction was issued, refusing to have two inspectors of the Food and Drug Administration come into your plant and inspect facilities? A. Yes, sir.

\* \* \* \* \*

April 18, 1974

\* \* \* \* \*

1092

Q. Mr. Ross, before we go on to the line of questioning we ended up with last night, did you make a determination of how many PEMF kits were shipped since July 18, 1972, within the United States?

\* \* \* \* \*

1093

A. I came up with 297.

Q. Can you from that investigation—can you tell us the names of the dealers that received them, names and addresses?

\* \* \* \* \*

A. Do you want me to read these into the record?

1094

Q. The amount shipped to the dealer and name and address.

A. X-ray Specialty Corporation, P.O. Box 23645, New Orleans, Louisiana.

Q. Is there an amount of that corporation? A. I don't have it here.

Q. O.K. A. Ross Medical Instrument, no relation, 350 Percival Avenue, Kinsington, Connecticut, 55.

Medical Electronics Inc., P.O. Box 529, Kernsville, North Carolina, 29.

\* \* \* \* \*

A. Robert Ford, 5331 Hamil Road, Elmonte, California, 30.

Faye Hassie, 1729 Carol Avenue, St. Paul, Minnesota.

\* \* \* \* \*

Professional Equipment Company, Route 1, Box 329,  
Bay Minette, Alabama, 10.

\* \* \* \* \*

1095

The Witness: Sierra Medical Sales, 3759 San Raphael,  
Riverside, California, 14.

Electromedics Incorporated, Benton Harbor, Michigan, 4.

Mark Stover, 9201 Northwestern, P.O. Box 14204 Okla-  
homa City, Oklahoma.

The Court: That was four?

The Witness: Two, I'm sorry.

The Court: Two?

The Witness: T-w-o, yes.

Mel Appel, 24. You have his address.

Doctors Coordinates, 36.

Gil Cook, 20.

Groves, 4.

Medical Aid Sales, 41.

The Court: Where is that Medical Aid Sales?

The Witness: That is in Brooklyn.

\* \* \* \* \*

## AFFIDAVIT OF MAILING

STATE OF NEW YORK  
COUNTY OF KINGS  
EASTERN DISTRICT OF NEW YORK, ss:

---DEBORAH J. AMUNDSEN---, being duly sworn, says that on the 29th  
day of October 1974---, I deposited in Mail Chute Drop for mailing in the  
U.S. Courthouse, Cadman Plaza East, Borough of Brooklyn, County of Kings, City and  
State of New York, a Brief for the Appellee-----  
of which the annexed is a true copy, contained in a securely enclosed postpaid wrapper  
directed to the person hereinafter named, at the place and address stated below:

Copal Mintz, Esq.-----

150 Broadway-----

New York, New York 10038-----

Sworn to before me this  
29th day of October 1974

Deborah J. Amundsen  
DEBORAH J. AMUNDSEN

Olga S. Morgan  
OLGA S. MORGAN  
Notary Public, State of New York  
No. 24-4501966  
Qualified in Kings County  
Commission Expires March 30, 1975